REMARKS

Status of the Claims

Claims 12, 14-18, 20, and 21 are pending. Claims 12 and 18 are independent. In this Reply, no claims have been amended, added, or cancelled. No new matter has been added.

Applicants respectfully request the Examiner to reconsider and withdraw the rejections in view of the following remarks.

Claim Rejections under 35 U.S.C. § 103

Claims 12-18, 20 and 21 stand rejected under 35 U.S.C. § 103(a) as allegedly unpatentable over Lee et al. (Obesity Research 1998) in view of Chaput et al. (Biochemical and Biophysical Research Communications 2000). In addition, claims 12, 14-18, 20 and 21 stand rejected under 35 U.S.C. § 103(a) as allegedly unpatentable over U.S. Patent No. 6,372,790 ("Bonhomme et al.") in view of Lee et al. and Chaput et al. Applicants respectfully disagree with these rejections; therefore, these rejections are respectfully traversed.

The presently claimed invention is directed to the use of a Perioxisome Proliferator Activated Receptor α (PPARα) agonist and metformin for the ***treatment of obesity***. The use of both a PPARα agonist and metformin in combination is especially effective to treat obesity, because the PPARα agonist and metformin, in combination, exhibit synergistic effects.

One embodiment of the invention, as presently claimed in independent claim 12, consists of administering to a patient in need thereof a pharmaceutical formulation consisting of an effective dosage of a PPARα agonist, an effective dosage of metformin and a pharmaceutical carrier, wherein the PPARα agonist is selected from the group consisting of fenofibrate, fenofibric acid and a pharmaceutically acceptable salt of fenofibric acid, wherein said effective dosage of the PPARα agonist and said effective dosage of metformin are effective for the treatment of obesity.

Another embodiment of the invention, as presently claimed in independent claim 18, consists of administering to a patient in need thereof a pharmaceutical formulation consisting of a first and second composition, wherein the first composition consists of an effective dosage of a PPARα agonist and a pharmaceutical carrier and the second composition consists of an effective dosage of metformin and a pharmaceutical carrier, wherein the PPARα agonist is selected from the group consisting of fenofibrate, fenofibric acid and a pharmaceutically acceptable salt of fenofibric acid, wherein said effective dosage of the PPARα agonist and said effective dosage of metformin are effective for the treatment of obesity.

In contrast, Bonhomme et al. discloses a pharmaceutical composition comprising: (i) metformin, (ii) a fibrate selected from fenofibrate and bezafibrate; and optionally one or more pharmaceutically acceptable excipients, suitable for use in the treatment of non-insulin dependent diabetes. See Abstract.

Lee et al. discloses that metformin decreases food consumption and induces weight loss in subjects with obesity with type II non-insulin-dependent diabetes. See Abstract.

Chaput et al. compares the effect of a PPARα activator, fenofibrate, and a PPARγ activator, rosiglitazone on body weight gain in (*fa/fa*) fatty Zucker rats and *db/db* mice. Abstract. According to Chaput et al, fenofibrate reduced body weight gain in the Zucker rats. However, fenofibrate had ***no significant effect*** on body weight gain in the *db/db* mice. See page 448, first column, second and third paragraphs.

The presently claimed methods of treating obesity are ***not*** an obvious combination of two active ingredients disclosed in the art to treat obesity. It may be true that "[i]t is *prima facie* obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose." M.P.E.P. § 2144.06 citing *In re Kerkhoven*, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980). However, contrary to the Office Action's assertions at pages 4 and 6, Lee

et al. and Chaput et al. do not teach that metformin and fenofibrate are useful for the same purpose. As discussed above, Lee et al. discloses that metformin induces weight loss in subjects with obesity with type II non-insulin-dependent diabetes. In contrast, according to Chaput et al., ***the effect of fenofibrate on body weight is unclear***. In the case of (*fa/fa*) fatty Zucker rats, fenofibrate decreased body weight gain. However, in the case of *db/db* mice, ***fenofibrate had no significant effect on body weight gain***. In fact, Chaput et al. discloses that the effect "fibrates on body weight gain...may depend on the animal model employed and the extent of hypertriglyceridemia." Page 449, first column, end of second paragraph. Accordingly, since the cited prior art does not disclose that both metformin and fenofibrate are individually useful for treating obesity, it is not *prima facie* obvious to combine metformin and fenofibrate to treat obesity.

Furthermore, one of ordinary skill in the art would not look to Bonhomme et al. to arrive at the presently claimed methods of treating obesity. The presently claimed methods utilize metformin and fenofibrate to treat ***obesity***. In contrast, as discussed above, Bonhomme et al. discloses the use of metformin and fenofibrate to treat ***non-insulin dependent diabetes***. Obesity and diabetes are distinct conditions, which require different and specific treatments. Thus, there is no reason for one of ordinary skill in the art searching for a composition efficient for treating obesity to read and take into account Bonhomme et al., which discloses compositions for treating diabetes. Accordingly, Bonhomme et al. is nonanalogous prior art, which is outside the scope and content of the prior art that should be used for analyzing the obviousness of the presently claimed methods.

Moreover, there is no reasonable expectation of success in using the compositions of Bonhomme et al. in the presently claimed methods of treating obesity. A *prima facie* case of obviousness requires a reasonable expectation of success in modifying or combining the elements of the prior art to arrive at the claimed invention. M.P.E.P. § 2143.02. The presently claimed methods treat

obesity. In contrast, as discussed above, the compositions of Bonhomme et al. are useful for treating ***diabetes***. Due to the differences between these conditions, one of ordinary skill in the art would ***not*** reasonably expect that Bonhomme et al.'s composition efficient in treating diabetes would be automatically efficient to also treat obesity. If one of ordinary skill in the art reasonably expected that a composition effective to treat diabetes automatically would also be effective to treat obesity, then one of ordinary skill in the art would reasonably expect that any and all anti-diabetic compounds automatically would be effective to treat obesity. However, one of ordinary skill in the art most certainly does not have such a reasonable expectation. Accordingly, there is no requisite reasonable expectation of success to combine Bonhomme et al. with Lee et al. and Chaput et al.

Therefore, for at least the reasons discussed above, withdrawal of the obviousness rejections over Lee et al. in view of Chaput et al. and over Bonhomme et al. in view of Lee et al. and Chaput et al. is respectfully requested.

Conclusion

In view of the foregoing remarks, the application is respectfully submitted to be in condition for allowance, and prompt, favorable action thereon is earnestly solicited.

If there are any questions regarding this Reply or the application in general, it would be appreciated if the Examiner could telephone the undersigned at 202-624-2845 so that examination of this application may be expedited.

If necessary to effect a timely response, this paper should be considered as a petition for an Extension of Time sufficient to effect a timely response, and please charge any deficiency in fees or credit any overpayments to Deposit Account No. 05-1323 (Docket # 102717.58257US).

Respectfully submitted,

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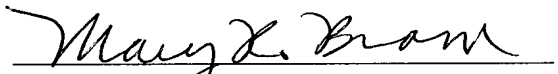

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